

To Export or Not to Export

Will the Medical Device Industry Continue to Thrive?



HEALTHCARE INDUSTRY UPDATE

Carleton McKenna & Co

TABLE OF CONTENTS

Key Takeaways	3
Macro Industry Overview	4
Demand Shift & Consolidation	5
Select Industry Transactions	7
Industry M&A Activity	8
Carleton McKenna Team & Track Record	9

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To Export or Not to Export *Will the Medical Device Industry Continue to Thrive?*

KEY TAKEAWAYS

Carleton McKenna is pleased to share its 4Q23 Medical Device report following [3Q23's Medtech Update](#). In this report, Carleton McKenna explores the strategic marketplace, consolidation trends and noteworthy transactions, as well as what the future deal making landscape may look like for brewery and alcoholic beverage businesses to help sector participants shape their strategies for the near- to medium-term.

1. **Decline in Medical Device Manufacturing Industry:** The industry has faced a steady decline over the past five years, attributed to post-pandemic supply chain disruptions, shorter product life cycles, and higher development costs for new technology.
2. **Shift Towards Patient-Centered Care:** The healthcare system is adapting to the needs of an aging population, with a focus on patient-centered, in-home care for chronic conditions, leading to a demand for transferable medical supplies and devices in non-traditional treatment settings.
3. **Performance Drivers Impact:** Positive and negative performance drivers, such as new import capabilities, consolidation of smaller operators, and government assistance opportunities, have shaped the industry landscape.
4. **Impact of Raw Material Prices:** Raw material purchases, especially natural gas and crude oil, significantly influence the pricing and cost fluctuations in medical device manufacturing, affecting upstream and downstream profit margins.
5. **Global Import-Export Dynamics:** Tariffs play a crucial role for US-based manufacturers, but international competition, particularly from Mexico and Germany, poses challenges. The decline in Germany's import market dominance is notable.
6. **Insurance, Regulation, and Market Consolidation:** Increasing insurance coverage under the Affordable Care Act has boosted demand for medical devices. However, regulatory changes and potential reimbursement rate reductions may impact both producers and healthcare providers. Major producers are expected to consolidate through mergers and acquisitions to remain innovative and competitive in the evolving market.

Carleton McKenna has substantive experience in the Healthcare industry, with a niche interest in the Medical Software and Devices segment. To learn more about Carleton McKenna's wide range of transaction experiences, strategies for growth or exit, and current Healthcare industry trends, please [contact us](#).

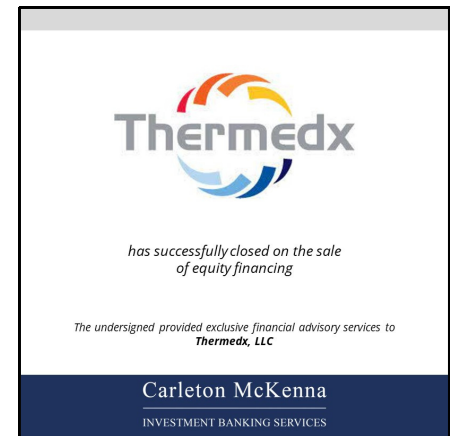
Medical Device Manufacturing industry revenue has been steadily declining over the past five years, due in part to post-pandemic supply chain disruptions, shorter product life cycles and higher costs of developing new technology. Healthcare systems are continually adjusting operations to account for the decrease in availability of supplies and the increasing size of an older population that requires greater medical assistance.

More specifically, the healthcare system is working to meet the needs of the older populations' interest in patient-centered, in-home care for chronic conditions. As patient sentiment shifts away from traditional healthcare spaces, including hospitals, urgent centers, and doctor's offices, the necessity of transferability for medical supplies and devices in non-traditional treatment settings has intensified.

The combination of performance drivers, both positive and negative, has led to (i) new import capabilities, (ii) the consolidation of smaller industry operators, and (iii) the opportunity for government assistance related to funding, technical support, and regulatory guidance within healthcare and medical devices industries¹.

Defining Limitations of Medical Device Manufacturing

The Medical Device Manufacturing industry is characterized by several products relating to electrotherapeutic apparatuses including but not limited to magnetic resonance imaging equipment (MRI), medical ultrasound equipment, pacemakers, hearing aids, and electromedical endoscopic equipment. Additionally, the industry manufactures irradiation apparatuses and tubes for medical diagnostic, medical therapeutic, industrial, research, scientific evaluation, and other applications. Manufacturers are regulated by various agencies including the Food and Drug Administration ("FDA") and the European Medicines Agency ("EMA")¹.



Relative to device production, raw material purchases and transportation have held the greatest impact in price and cost fluctuations related to upstream and downstream profit margins. As the price of raw materials increases, so does the price of medical devices in the wholesale market. These raw materials include natural gas and crude oil, the two main components necessary for FDA approved thermoplastic and polyurethane medical applications².

Import and Export Markets for Expansion

Tariffs are critical to US-based manufacturers of plastics and resins. Downstream wholesaling of medical devices from Mexico and Germany, direct competitors to US manufacturers, circumvent the protections placed on upstream domestic producers. The availability of international manufacturers and wholesalers vying for market share in the US provides cost savings to US customers through the importation of medical devices.

The international availability for medical devices will not only continue to take money out of the hands of the American economy, but overall manufacturing revenue across the globe will decline with the world price of natural gas. Similarly, the lack of aggressive product pricing, that has remained reliant on input costs, and an increase in market competition will only assist in the creation of an oversaturated market for medical devices in the US. Should this trend continue in the market, US-based medical device wholesalers should expect to see continued decline in profit margins if they do not remain competitive with pricing.

Germany's Role as Importer Extraordinaire Opposite Mexico

Prior to the economic decline following the global pandemic, Germany served as the largest source of imports for medical devices. Exports alone accounted for one-fourth of domestic manufacturers' revenue and imports satisfied one-third of domestic demand for medical devices. Most notably, Germany has suffered at the hands of lower production costs by Mexican medical device manufacturers. With Mexico's proximity to the US market, Germany has slowly lost their hold on the import market over the last five years and is expected to continue to decline.

Similar to the shift in import and export necessity, the strengthening of the US dollar over has negatively affected the value of exports abroad due to their higher price point. However, considering the forecasted decline US dollar value, the value and revenue potential behind medical device exports is expected to surge².

Availability of Plastics and Resins Abroad

Pricing structures established by manufacturers and wholesalers of plastics accounted for downstream revenues of \$134 billion and profits of almost \$10 billion, respectively. A cut to either industry KPI will have an adverse effect on supply and demand for medical devices in the United States¹. According to IBISWorld's Plastic and Resin Manufacturing Report, exports have remained a source of consistent demand for manufacturers for emerging economies like Mexico, which is experiencing an expansion of their middle class.

Current volatility of plastic and resin availability in relation to the emergence of Mexico's manufacturing capabilities at lower costs are expected to shift how products and services are segmented within the US market. As of 4Q 2023, electromedical devices for surgical applications, irradiation apparatus', and other disposable and non-disposable tubing applications may no longer remain the largest US revenue and profit producers.

Insurance Supports Medical Device Demand

While manufacturers are looking to circumvent expenses during the production process, consumers are leveraging their insurance to cover increasing healthcare costs. Broader access to insurance under the Patient Protection and Affordable Care Act ("Affordable Care Act") increased public and private health spending³. As patients continue to become insured, in conjunction with an aging population, healthcare prices will continue to weaken and inversely boost demand for medical device products. Similarly, as the Affordable Care Act represents the effort to reframe the financial relationship between Americans and the healthcare system, the opportunity to generate revenue will remain, regardless of price volatility for producers.



Looking into the future, continued regulatory changes can place higher strain on US producers looking to bring new products to market. Similarly, the continuation of reimbursement policies via the Affordable Care Act and additional insurance providers could adversely affect the demand of medical devices by patients. Consumers will remain less inclined to use devices that are not easily accessible or covered by their insurance. This potential loss of revenue could be compounded with the reduction of reimbursement rates that will negatively impact the demand for medical devices by healthcare providers¹.

Consolidation Efforts by Major Producers

For medical device manufacturers looking to maintain market share, the need for more effective and efficient products will only continue. The improvement of polymer coating methods and the development of new materials that can withstand high-stress environments, high temperatures, and other harsh conditions will need to be a primary focus both for market share security and a revenue boost.

Similarly, medical device producers should look to focus on developing personalization techniques to create products that are tailored to the needs of individual patients – an outcome related to non-traditional care methods preferred by an aging population. Most notably, the post-pandemic need for remote monitoring of patients' health without the need for unnecessary hospital or clinic visits should be top of mind for producers when building out their medical device use cases¹.

The importance of research and development will increase as a result of the expected needs of aging patients. With that, the balance of costs and profits will determine the health of medical device manufacturers. For those smaller industry operators that cannot maintain balance, the opportunity to leverage their manufacturing capabilities has the potential to generate a greater value for their business. Merger and acquisition activity is forecast to increase as larger medical device manufacturers look to remain innovative across product and service capabilities.

Boston Scientific

has acquired



Boston Scientific Corporation (NYSE: BSX) acquired a majority stake in Acotec Scientific, a Beijing-based medtech focused on cardiovascular treatment devices. Acotec and its almost 500 employees maintain a portfolio of drug-coated balloons and percutaneous transluminal angioplasty hardware, typically used to unclog arteries, and radiofrequency ablation catheters, all manufactured and approved in China.

Boston Scientific expects completion of the partial offer to further strengthen their presence in China and create the potential for commercialization of Acotec products globally, providing an increased number of physicians and patients access to their robust and complementary product portfolios.

The acquisition will give Boston Scientific greater access to the Chinese market, which Boston Scientific expects will account for 25% of the global medtech demand by 2030⁴.



has acquired



Shockwave Medical, Inc. (NASDAQ: SWAV), a pioneer in the development of Intravascular Lithotripsy (IVL) to treat severely calcified cardiovascular disease, announced it has entered into a definitive agreement to acquire Neovasc Inc. (NASDAQ,TSX: NVCN), a specialty medical device company that develops, manufactures, and markets products for the rapidly growing cardiovascular marketplace. Its products include Reducer, for the treatment of refractory angina, which is under clinical investigation in the U.S. and has been commercially available in Europe since 2015.

The Neovasc Reducer System is a first-of-its-kind technology to address refractory angina, a chronic condition in which a patient suffers chest pain that cannot be controlled by conventional therapies.

Shockwave Medical acquired all outstanding Neovasc shares for an upfront cash payment of \$27.25 per share, corresponding to an enterprise value of approximately \$100 million, inclusive of certain deal-related costs. Neovasc shareholders will also receive a potential deferred payment in the form of a non-tradable contingent value right entitling the holder to receive up to an additional \$12 per share in cash if certain regulatory milestones are achieved.

Shockwave Medical is focused on developing and commercializing products intended to transform the way calcified cardiovascular disease is treated. Shockwave Medical aims to establish a new standard of care for the interventional treatment of atherosclerotic cardiovascular disease through differentiated and proprietary local delivery of sonic pressure waves for the treatment of calcified plaque⁵.

SELECT TRANSACTION ACTIVITY⁶

Date	Target	Target Description	Acquirer	Deal Value
9/29/2023	Apple Homecare Medical Supply	Provider of home medical equipment intended to focus on respiratory care for children. The company's service and product offerings include respiratory supplies, enteral feeding supplies, nutrition supplies, urological supplies and diabetic supplies.	InTandem Capital Partners	Undisclosed
9/1/2023	NuVasive	Medical technology company focused on developing, manufacturing, selling and providing integrated spine surgery solutions, including surgical access instruments, spinal implants, fixation systems, biologics, and enabling technologies.	Globus Medical (NYS: GMED)	\$3.1B
7/24/2023	Diros Technology	Manufacturer of surgical devices intended to offer radiofrequency products used to treat chronic pain conditions.	Avanos Medical (NYS: AVNS)	\$60.0M
5/11/2023	Lotus Surgicals	Manufacturer of medical devices and surgical instruments focused on the wound closure segment.	Murugappa	\$42.5M
5/10/2023	Audio Technologies	Manufacturers of medical devices and surgical instruments intended to serve customers and medical companies.	Innovative-RFK	Undisclosed
4/11/2023	Neovasc	Specialty medical device company that develops, manufactures and markets products for the rapidly growing cardiovascular marketplace.	ShockWave Medical (NAS: SWAV)	\$147.0M
4/4/2023	Apollo Endosurgery	Medical technology company engaged in the design, development and commercialization of medical devices to advance gastrointestinal therapeutic endoscopy.	Boston Scientific (NYS: BSX)	\$636.0M
2/8/2023	Acotec Scientific	Medical device company focused on providing "leave nothing behind" treatment solutions for vascular diseases.	Boston Scientific (NYS: BSX)	\$523.9M
1/6/2023	SteriCare Solutions	Manufacturer of medical supplies such as irrigation syringes, tube holders, surgical cables, catheter trays.	Spinnaker International	Undisclosed
12/2/2022	Laboratoires Vivacy	Manufacturer of injectable medical devices intended to be used by plastic surgeons, dermatologists and aesthetic physicians.	Bridgepoint Advisers (LON: BPT)	\$954.8M
10/13/2022	Symmetry Surgical	Manufacturer of disposable surgical supplies and specialty medical products intended for the healthcare sector.	Aspen Surgical	Undisclosed
9/30/2022	IZI Medical Products	Manufacturer of medical devices used in interventional radiology and oncology, radiation therapy, neuro-spine and image-guided surgery procedure.	Halma	\$97.4M
2/2/2022	Tensentric	The company engages in the design, engineering, prototyping, assembly and manufacturing of diagnostics systems, providing clients with equipment for complex system design.	GenNx360 Capital Partners	\$35.0M



Paul H. Carleton

Managing Partner

Paul has more than thirty years experience in corporate and investment banking focusing on mergers and acquisitions and capital raising activities for both private and public corporations. Prior to establishing Carleton McKenna, Paul was founder and Senior Managing Director of Carleton, McCreary, Holmes & Company, a position he maintained through the firm's life span and acquisition by KeyCorp in 1996. Paul was previously a Partner, Member of the Board of Directors, Senior Managing Director and Head of Corporate Finance at the regional investment banking firm of McDonald & Company.

Paul has broad experience serving on the boards of both private and public corporations. He currently serves on the boards of Baldwin-Wallace University, University Hospitals Case Medical Center, Playhouse Square Foundation, E&H Family Group (Buehler's Fresh Foods) and Bluecoats. He has also held numerous civic positions including President of Leadership Cleveland Alumni Association and Trustee of Northwestern University Alumni Association.

Paul holds a Bachelor's degree from Baldwin Wallace University and an M.B.A. from Northwestern University.



Christopher J. McKenna

Managing Partner

Before joining Carleton McKenna, Chris acquired a Cleveland manufacturing business where he was President and CEO. Previously, Chris was the Director of Financial Analysis with the MacLean-Fogg Company in Chicago where he executed on financial transactions and corporate development and also managed a business unit. Prior to that time, Chris was an Associate with the investment banking firm of Rodman & Renshaw in New York, where he was involved with private and public transactions to raise equity, subordinated and senior debt. He began his career in commercial banking in New York with Manufacturers Hanover Trust and Security Pacific Business Credit.

Chris serves on the boards of numerous private corporations. Currently, he serves on the board of The First Tee of Cleveland, the Leadership Council of University Hospitals Ahuja Medical Center and the CHAMPS Healthcare affiliate of The Center for Health Affairs.

Chris received his B.A. in Economics from Dartmouth College and his M.B.A. with High Distinction from the University of Michigan Business School.



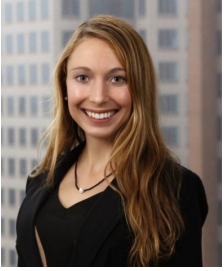
Nora T. Mahoney

Managing Director

Nora has experience with securities regulation, corporate governance, commercial litigation and broker dealer registrations. Nora is primarily responsible for the execution of capital raisings and private placement assignments across a variety of industries, as well as M&A advisory for business owners.

Prior to joining Carleton McKenna, Nora worked for Attorney General Mike DeWine and then practiced Commercial Litigation with a national law firm where she was involved in pre-trial practice for securities litigation.

Nora was awarded her Juris Doctor and Masters from Vermont Law School and serves as a Board Member for First Federal of Lakewood and as an executive Board Member for the Union Club of Cleveland. She formerly served on the Board of Trustees for Baldwin Wallace University, from where she received her Bachelors in Biology and Sustainability. She participates as a Committee-Member for the Association of Corporate Growth's Women in Transactions group, is Chair of Cleveland's Women in Finance, and is a member of several bar associations and the Leadership Cleveland Class of 2023.



Alexis M. Becker

Vice President

Alexis works alongside the Carleton McKenna senior management team and is responsible for developing and reviewing transaction materials for M&A and capital raise opportunities, conducting financial analysis, identifying strategic and financial partners for clients, facilitating due diligence processes, as well as managing the firm's industry research and marketing strategy.

Prior to joining Carleton McKenna, Alexis worked in project management at Akron-based marketing firm, WhiteSpace Creative, where her experience with market research, analytics and strategic planning enabled her to lead a team of graphic designers and copywriters to a gold medal at the 2017 National Addy Awards. At the firm, she was responsible for the planning, execution and analysis of marketing strategies for clients.

Alexis received her M.B.A in Business Administration from Baldwin Wallace University in May 2018. She received her B.S. in Business Administration from the Honors Program at Edinboro University of Pennsylvania.



David T. Jeziorowski

Analyst

David is an Analyst at Carleton McKenna & Company. His current job responsibilities include industry and sell-side flow research, as well as creation of buyers lists, pitches and other transaction documents.

Before joining Carleton McKenna, David worked as a research and investment intern at Praetorian Holdings Group, a Cleveland-based private equity firm. During his internship, David performed extensive research on Industrial and Renewable Energy industries, communicated directly with sell-side M&A advisors and executed business and financial analysis utilized by members of the firm's investment committee.

David graduated from the University of Dayton in May 2022 where he received his B.S. in Business Administration with a concentration in Finance.



Emily A. Kuznik

Marketing Analyst

Emily is a Marketing Analyst at Carleton McKenna & Company. Her primary responsibilities include researching and developing marketing content and industry reports, enacting website development, maintaining a social media strategy and regulating web-based management services.

Prior to joining Carleton McKenna, Emily worked as a Leadership Development Fellow for Baldwin Wallace University's Carmel Boyer School of Business. As a member of the pilot program, she coordinated a variety of marketing initiatives for both graduate and undergraduate programs including social media and email marketing campaigns, advertising, event planning, and recruiting.

She graduated magna cum laude from Baldwin Wallace University in 2021 where she earned a B.A. in Digital Marketing and again in 2022 with an M.B.A. in Management.

Centura Imaging

has been acquired by

Test Equipment Distributors

The undersigned provided exclusive financial advisory services to Centura Incorporated

Carleton McKenna
INVESTMENT BANKING SERVICES

NEUROS MEDICAL

has successfully closed on the sale of equity financing

The undersigned provided exclusive financial advisory services to Neuros Medical, Inc.

Carleton McKenna
INVESTMENT BANKING SERVICES

Project Immunity

Developer of proprietary cytotoxic T lymphocyte (T-Cell) based vaccines and treatments

The undersigned provided exclusive financial advisory services to Project Immunity

Carleton McKenna
INVESTMENT BANKING SERVICES

TherEX

has been acquired by

Kindred Healthcare
(NYSE: KND)

The undersigned provided exclusive financial advisory services to TherEX, Inc.

Carleton McKenna
INVESTMENT BANKING SERVICES

Project Everest

Producer of powerful and compact pain management device that uses thermoelectric technology to provide heating and cooling therapy

The undersigned provided exclusive financial advisory services to Project Everest

Carleton McKenna
INVESTMENT BANKING SERVICES

skinklinic

has successfully closed on the sale of equity financing

The undersigned provided exclusive financial advisory services to Skinklinic

Carleton McKenna
INVESTMENT BANKING SERVICES

Thermedx

has successfully closed on the sale of equity financing

The undersigned provided exclusive financial advisory services to Thermedx, LLC

Carleton McKenna
INVESTMENT BANKING SERVICES

WHOLE HEALTH

has successfully closed on the sale of equity financing

The undersigned provided exclusive financial advisory services to Whole Health

Carleton McKenna
INVESTMENT BANKING SERVICES

CORNERSTONE INDUSTRIAL GROUP

has acquired

RHOPAC

The undersigned provided exclusive financial advisory services to Cornerstone Industrial Group, LLC

Carleton McKenna
INVESTMENT BANKING SERVICES

RESEARCH ORGANICS
ISO 9001 - 2000 CERTIFIED

has been acquired by

SIGMA-ALDRICH
(NASDAQ: SIAL)

The undersigned provided exclusive financial advisory services to Research Organics, Inc.

Carleton McKenna
INVESTMENT BANKING SERVICES

Project Flight

Provider of international aerial critical care and organ transportation and charter services

The undersigned provided exclusive financial advisory services to Project Flight

Carleton McKenna
INVESTMENT BANKING SERVICES

Formfire

has been acquired by

agencybloc
a portfolio company of

RESURGENS TECHNOLOGY PARTNERS

The undersigned provided exclusive financial advisory services to FormFire

Carleton McKenna
INVESTMENT BANKING SERVICES

COMS Interactive

has successfully closed on the sale of \$6.25 million of equity financing from



SUMMIT PARTNERS

The undersigned provided exclusive financial advisory services to COMS Interactive, LLC

Carleton McKenna
INVESTMENT BANKING SERVICES

TESTOIL
REMARKABLE IN EVERY WAY

has been acquired by

eurofins

The undersigned provided exclusive financial advisory services to Insight Services, Inc. (dba Testoil)

Carleton McKenna
INVESTMENT BANKING SERVICES

Project Premier

National Group Purchasing Organization providing members with account management, sales and contracting services

The undersigned provided exclusive financial advisory services to Project Premier

Carleton McKenna
INVESTMENT BANKING SERVICES

Performance Health
TOTAL HEALTH PLAN SOLUTIONS

has been acquired by

LIBERTY

The undersigned provided exclusive financial advisory services to Performance Health

Carleton McKenna
INVESTMENT BANKING SERVICES

ENDNOTES

1. <https://www.ibisworld.com/united-states/market-research-reports/medical-device-manufacturing-industry/>
2. <https://www.ibisworld.com/united-states/market-research-reports/plastic-resin-manufacturing-industry/>
3. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3001814/>
4. <https://www.prnewswire.com/news-releases/boston-scientific-announces-strategic-investment-to-acquire-majority-stake-of-acotec-scientific-holdings-limited-301699901.html>
5. <https://shockwavemedical.com/about/press-releases/shockwave-medical-completes-acquisition-of-neovasc/>
6. <https://www.pitchbook.com/>